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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,018	12/21/2001	Mark G. Erlander	485772004300	2946

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EXAMINER

ZEMAN, MARY K

ART UNIT PAPER NUMBER

1631

DATE MAILED: 01/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/028,018	Applicant(s) ERLANDER ET AL.	
	Examiner Mary K Zeman	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 September 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 15-21 and 30-48 is/are pending in the application.
- 4a) Of the above claim(s) 42 and 43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-21, 30-32 and 44-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 42, 43 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 15-21, 30-48 are pending in this application. Claims 33-48 are newly added. Newly submitted claims 42 and 43 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: They use differing sets of polynucleotides. Claims 42 and 43 replace the assaying step of claim 20 to utilize the polynucleotides of Tables 7 and 8 which were not originally under examination. These sets of polynucleotides are materially different than the sets which exist in Tables 2-5, as set forth in the previous restriction requirement, and would require additional search and consideration. Applicant indicates that support for claims 42 and 43 was originally provided in claims 13 and 14, which the examiner notes, were not originally examined, as they were drawn to a separate and distinct invention. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 42 and 43 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Applicant's arguments filed 9/8/04 have been fully considered but they are not persuasive. Any rejection not repeated below has been withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### **Rejections Maintained**

Claims 15-21 and 30-32 remain rejected and new claims 33-41, and 44-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons set forth in the previous Office Action. To the extent this rejection is newly applied, it is necessitated by Applicant's amendments.

Applicant's arguments have been carefully considered and are not deemed persuasive.

Regarding Applicant's arguments regarding the Written Description Guidelines, Applicant is assured that the Examiner has thoroughly reviewed and properly applied this rejection. Applicant's comments regarding issued US Patents have been considered, but Each Application is examined on its own merits, and issued patents are assumed valid. Arguing both the written description and art rejections together is inappropriate, as each rejection is assessed on its own merit. Applicants extensive arguments regarding the validity of the prior art rejections do not remedy the defects of the instant specification. The rejection under written description is based on fact- what is specifically disclosed in the application as originally filed.

Applicant argues that merely stating a name that supposedly identifies a particular human gene sequence is adequate written description for assays for staging breast cancer samples by assaying for expressions of those genes. This has previously been addressed. The specification does not provide enough information for one of skill in the art to be able to obtain the proper sequences of the allegedly identified genes in order to make the arrays required. As set forth previously, the Tables do not provide specific sequences, or reliable stable means of obtaining them. Many many of the "genes" are merely labeled EST which is a generic term for a portion of an expressed sequence which has no known identity or function. The CloneID numbers are referencing a non-stable website which does not provide adequate written description of the referenced sequences.

Applicant's assertions that a representative sample of genes is provided such that they have basis for claiming any and all sequences which may, in the future, be linked to some stage of breast cancer are not persuasive. None of the sequences provided share any common sequence or structure such that a related genus of polynucleotides is immediately envisaged. Each of the multitude of allegedly identified genes or sequences has a differing polynucleotide sequence, and function. As such, there is no structural or functional basis for identifying what sequences could be used in the invention.

The claims encompass a genus of polynucleotides defined only by an asserted association with a disease state (not even a function of the polynucleotide itself) wherein the relationship between the structure of the members of the genus and the asserted association (function) has not been defined. The specification does not set forth what identifies a polynucleotide as being useful in the assays of the invention. In the absence of such a relationship either disclosed in the

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as file application or which would have been recognized based upon information readily available to one skilled in the art, the skilled artisan would not know how to make/use compounds (polynucleotides) that lack structural definition. The fact that one could have assayed a compound of interest using the claimed assays does not overcome this defect since one would have no knowledge beforehand as to whether or not any compound would fall within the scope of what is claimed.

Claims 15-21, and 30- 41 and 44-48 remain rejected under 35 U.S.C. 102(e) as being anticipated by Hung (USP 6,642,009).

Applicant's arguments have been carefully considered, and are not deemed persuasive. In regards to Applicant's comments as to the validity of the Hung patent, or its disclosure, each US Patent as assumed valid on its face. In regard to the argument that Hung does not disclose the use of multiple markers in the analysis, Applicant is pointed to column 6, lines 54-57 where in Hung states that any one or more of the listed markers can be tested. This includes 5 or more. Relative expression levels of the markers are one of the many characteristics Hung notes can be evaluated. Applicant lists certain markers and notes their lack of disclosure in Hung, however, those markers are not specifically set forth in the claims, nor are any claims limited to those markers.

Hung (USP 6,642,009) discloses methods of staging a breast cancer ductal lavage sample. The lavage samples are examined to determine the presence of a marker associated with breast cancer, or pre-cancer (staging). A number of differing markers are specifically identified as markers of interest in staging breast cancer, including CEA (col 1), p53 (col 4), and G-actin (col 4), LPA (col 6), paladin (col 6) and all the markers at columns 7-9, 14-15 and claims 4 and 15. Stages of breast cancer studied by Hung include hyperplasia, ADH, LG-DCIS, HG-DCIS, pre cancerous, normal, invasive carcinoma (column 9). mRNA from the sample can be assessed. As such, Hung anticipates the rejected claims.

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***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

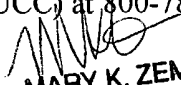
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (571) 272 0723

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

  
MARY K. ZEMAN  
PRIMARY EXAMINER  
4/16/04  
11/5/04